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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,228	09/29/2003	Samir M. Hanash	31755-A-PCT-USA-I	1891

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,228	HANASH ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *5-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/3/05, ~~6/11/05~~*. 7/11/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 1, claims 1-4 in the reply filed on 06/06/2005 is acknowledged. The traversal is on the ground(s) that the instant application should follow the Restriction Requirement of the parent case. Applicant also argues that group 1, and claims 10-14 are related. These arguments have been fully considered but found unpersuasive. As noted in the previous Office action, claims 5-14, drawn to method of cancer diagnosis by detecting autoantibodies specific for a beta-tubulin isoforms or yet to be identified protein; Claims 15-17, drawn to method of stimulating an immune response to a beta-tubulin isoforms or yet to be identified protein , classified in class 424, subclass 184.1; Claim 18, drawn to composition comprising a yet to be identified protein, classified in class 530, subclass 350; Claims 19-21, drawn to composition comprising an antibody binding to a protein yet to be identified by the method described in claim 1, classified in class 530, subclass 387.1. These different inventions are different inventions because the elected group I is to screen a protein that induces in vivo autoantibody production, group II is to cancer diagnosis method using a beta-tubulin isoforms, or the protein that has to be screened in group I method, and group II is to treatment method. Groups IV, and V are drawn to different products, namely proteins, and antibodies to said proteins, the nature of the proteins not to be discovered by the claimed method described in group I invention.

The polypeptide of group II and the antibody of group III are patentably distinct for the following reasons: While the inventions of antibody and polypeptides are

polypeptides, in this instance the polypeptide is a single chain molecule that carries out a biological function, whereas the polypeptide of antibody group encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope of the polypeptide. Thus the polypeptide and the antibody are structurally distinct molecules; any relationship between a polypeptide and an antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Searching the antibody and polypeptide inventions would impose a serious search burden, given the identity of the polypeptide has yet to be identified by the group I invention. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies group. Furthermore, antibodies which bind to an epitope of a polypeptide may be known even if a polypeptide is novel. patentably distinct.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group

requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 are pending and claims 1-4 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, in step (d) recites "antiserum" from a subject, and in step (e) recites the patients "serum". It is not clear whether "antiserum" and "serum" are two different entities or the single entity. If they are two different entities, then the claims do not make any sense in terms of what is being detected. For the purpose of this Office action, the Office will interprets the two different terminologies referring to the same entity, i.e. serum sample from a subject having a cancer, wherein the serum sample contains autoantibodies that the normal control serum sample does not contain. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al., IDS filed on 07/11/2005, J Cancer Res Clin Oncol. 1988;114(2):204-7.

Claims 1-4 are drawn to method of identifying proteins that induces autoantibodies in cancer patients, comprising the steps of isolating proteins from cancer cells, more specifically cells derived from the subject's tumor (claim 2), or from a continuous cell line representative of the subject's tumor (claim 3), followed by subjecting isolated proteins to two-dimensional PAGE, followed by Western blot analysis with sera from cancer patients as compared to sera from normal control patients, wherein the proteins bound by antibodies present in the cancer patients serum but not the normal control serum are identified as proteins to which a subject with cancer produces autoantibodies. Since the specification does not defined the limitation "derived from the subject's tumor" in claim 2 and "derived from a continuous cell line representative of the subject's tumor" in claim 3, the limitations are broadly interpreted as the cells that are being used to isolate the proteins being subjected to two-dimensional analysis are from the same type of cancer cells as the patient who provides the serum containing autoantibodies.

Hirsch et al., at method of identifying proteins that induces autoantibodies in Hodgkin's disease which is a form of cancer, i.e. lymphoma, comprising the steps of isolating proteins from L428 cancer cells derived from Hodgkin's disease cancer patients, followed by subjecting isolated proteins to two-dimensional PAGE, followed by Western blot analysis with sera from cancer patients as compared to sera from normal control patients, wherein the proteins bound by antibodies present in the cancer patients serum but not the normal control serum are identified as proteins to which a subject with cancer produces autoantibodies. Note page 204 under the heading Materials and methods for the gel-electrophoresis, and Western blot, and the picture of the identified proteins in the two-dimensional gel at Fig. 1A, 2, 3. Schaadt et al., Int J Cancer. 1980 Dec 15;26(6):723-31 are provided to present evidence that L428 used in Hirsch et al., are cells derived from the subject's tumor and from a continuous cell line representative of the subject's tumor. In other words, the cells being used are derived from Hodgkin's disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D
Examiner
Art Unit 1642